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International Bureau

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Published
With international search report.

(54) Title: DIAGNOSIS AND THERAPY OF PREMATURE OVARIAN FAILURE

(57) Abstract

This invention relates to methods by which a predisposition to Premature Ovarian Failure (POF) can be determined. In particular, it relates to methods for detecting whether a female has a predisposition to POF with reference to an alteration (mutation) in the gene encoding inhibin.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ00/00021

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: C12Q 1/68, A61K 48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC[7] A61K, C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
STN CAPLUS, MEDLINE, WPIDS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FEBS letters, vol. 206(2), 329-34; Stewart, A.G. et al. (1986) Human inhibin genes, October 1986.	1-14
A	Biochemical and biophysical research communications, vol. 135 (3), 957-64; Mason, A.J. et al. (1986) Structure of two ovarian inhibins, 28 March 1986.	1-14
A	Endocrinology, vol. 139, no. 7, 3271-79; Ardekani, A.M. et al.(1989) Structure of the Rat Inhibin and Activin B_A-Subunit Gene and Regulation in an Ovarian Granulosa Cell Line, July 1998.	1-14

[X] Further documents are listed in the continuation of Box C [] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" Earlier application or patent but published on or after the international filing date

"L" Document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" Document referring to an oral disclosure, use, exhibition or other means

"P" Document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 May 2000	9 JUNE 2000
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**DAVID HENNESSY** Telephone No : (02) 6283 2255

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ00/00021

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Fertility and Sterility, vol.70, no.5, 907-12; Petraglia, F. et al. (1998) Low levels of serum inhibin A and inhibin B in women with hypergonadotropic amenorrhea and evidence of high levels of activin A in women with hypothalmic amenorrhea, November 1998.	
A	Science, vol. 239, 1296-99; Woodruff, T.K. et al. (1988) Dynamic Changes in Inhibin Messenger RNAs in Rat Ovarian Follicles During the Reproductive Cycle, 11 March 1988.	

Copy for the Elected Office (EO/US) PCT/NZ00/00021

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

HAWKINS, Michael, Howard
Baldwin Shelston Waters
NCR Building
342 Lambton Quay
Wellington 6001
NOUVELLE-ZÉLANDE

Date of mailing (day/month/year)
19 December 2000 (19.12.00)

Applicant's or agent's file reference
JM503299/142

IMPORTANT NOTIFICATION

International application No.
PCT/NZ00/00021

International filing date (day/month/year)
25 February 2000 (25.02.00)

1. The following indications appeared on record concerning:

[] the applicant [] the inventor [X] the agent [] the common representative

Name and Address

BENNETT, Michael, Roy
West-Walker Bennett
Mobil on the Park
157 Lambton Quay
Wellington
New Zealand

State of Nationality:

State of Residence:

Telephone No.: 64 4 499 9058

Facsimile No.: 64 4 499 9306

Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [] the name [] the address [] the nationality [] the residence

Name and Address

HAWKINS, Michael, Howard
Baldwin Shelston Waters
NCR Building
342 Lambton Quay
Wellington 6001
New Zealand

State of Nationality:

State of Residence:

Telephone No.:

Facsimile No.:

Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[] the International Searching Authority
[] the International Preliminary Examining Authority
[] the designated Offices concerned
[X] the elected Offices concerned
[] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Catherine Massetti

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 October 2000 (09.10.00)	
International application No. PCT/NZ00/00021	**Applicant's or agent's file reference** 25611 MRB
International filing date (day/month/year) 25 February 2000 (25.02.00)	**Priority date** (day/month/year) 25 February 1999 (25.02.99)
Applicant SHELLING, Andrew, Neil	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

15 September 2000 (15.09.00)

[] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Charlotte ENGER
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

20 OCT 2000

WIPO PCT

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
25611 MRB		
International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/NZ00/00021	25 February 2000	25 February 1999

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] C12Q 1/68, A61K 48/00

Applicant

AUCKLAND UNISERVICES LIMITED et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☒	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
15 September 2000	11 October 2000
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**DAVID HENNESSY** Telephone No. (02) 6283 2255

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NZ00/00021

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[] the language of publication of the international application (under Rule 48.3(b)).

[] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[] contained in the international application in written form.

[] filed together with the international application in computer readable form.

[] furnished subsequently to this Authority in written form.

[] furnished subsequently to this Authority in computer readable form.

[] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [] The amendments have resulted in the cancellation of:

[] the description, pages

[] the claims, Nos.

[] the drawings, sheets/fig.

5. [] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

 ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

 ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1).

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Priority document NZ 334386 was not sighted by the examining authority. As there is no issue of anticipation in the International Search Report, the issue of priority was not considered during international examination.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**1-14**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-14**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-14**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Novelty (N) and Inventive Step (IS)

While the detection of alterations in the gene encoding inhibin may lack inventive step over the cited documents in the International Search Report, the method of the claims 1-10 is defined in terms of detecting predisposition to premature ovarian failure. None of the cited documents either discloses or suggests such a method. Consequently claims 1-10 are novel and inventive over the citations. Similarly none of the citations disclose or suggest the use of therapies defined by claims 11-14. Claims 11-14 are novel and inventive over the citations.

The problem solved by the claimed invention, premature ovarian failure detection and treatment, is not linked by any of the citations to the solution of the claimed invention, detection and treatment of inhibin mutations. This is an inventive step over the cited documents.

Industrial Applicability (IA)

There are no unified criteria for the industrial applicability of therapeutic methods. Claims 11-13 may fail the requirements of industrial applicability in countries that have adopted European Patent Office examining guidelines. On their face, the claims all have industrial applicability in the fields of diagnostics and therapeutic goods and methods.